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Interdisciplinary management of acute ischaemic stroke – current evidence on training requirements for endovascular stroke treatment. Position Paper from the ESC Council on Stroke and the European Association for Percutaneous Cardiovascular Interventions with the support of the European Board of Neurointervention: A step forward

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Abstract

Stroke, a vascular disease of the brain, is the #1 cause of disability and a major cause of death worldwide. Stroke has a major negative impact on the life of stroke-affected individuals, their families and the society. A significant proportion of stroke victims indicate that they would have preferred death over their after-stroke quality of life. Mechanical thrombectomy (MT), opening the occluded artery using mechanical aspiration or a thrombus-entrapment device, is a guideline-mandated (class I, level of evidence A) treatment modality in patients with large vessel occlusion stroke. MT clinical benefit magnitude indicates that a universal access to this treatment strategy should be the standard of care. Today there is a substantial geographic variation in MT deliverability, with large-scale disparities in MT implementation. In many countries effective access to MT remains severely limited. In addition, many of the MT-treated

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patients are treated too late for a good functional outcome because of logistic delays that include transportations to remotely located, scarce, comprehensive stroke centres. Position Paper from the European Society of Cardiology Council on Stroke and European Association for Percutaneous Cardiovascular Interventions on interdisciplinary management of acute ischaemic stroke, developed with the support of the European Board of Neurointervention fills an important gap in systematically enabling interventional cardiologists to support stroke intervention in the geographic areas of unmet needs in particular. We review strengths and weaknesses of the document, and suggest directions for the next steps that are swiftly needed to deliver MT to stroke patients more effectively.

Key words: acute ischaemic stroke, mechanical thrombectomy, cerebral resuscitation, unmet needs, cardiology cathlab-based treatment, multispecialty team.

Stroke, a vascular disease of the brain, is the number 1 cause of disability and a major cause of death worldwide [1, 2]. Stroke has a major negative impact on the life of stroke-affected individuals, their families and society [2]. With conservative stroke management, a significant proportion of stroke victims would have preferred death over their after-stroke quality of life [3]. Despite unquestionable progress in pharmacologic and non-pharmacologic prevention, the burden of cardiovascular disease (including stroke) will not be decreasing – but increasing – over the next 25 years [4].

Mechanical thrombectomy (MT), opening the occluded artery using mechanical aspiration [5, 6] or a thrombus-entrainment device [6], is a guideline-mandated (class I, level of evidence A) treatment modality in patients with large vessel occlusion stroke that constitutes at least 15% of ischaemic strokes [2] (note that several consecutive patient series show that this proportion may be significantly higher, reaching ~30–45% [1, 7]). MT, if administered timely, translates into at least a 2-fold increase of the likelihood of a good functional outcome (functional independence after stroke) [8, 9]. The magnitude of the MT clinical benefit indicates that universal access to this treatment strategy should be the standard of care [2, 6]. The basis of MT clinical efficacy is its rapid delivery in a maximally achievable proximity to the disease onset place, as patient transportations for MT are associated with prolongation of ongoing cerebral tissue loss and worsened clinical outcomes [10–13].

Today, in Europe and worldwide, there is substantial geographic variation in MT deliverability, with large scale disparities in MT implementation between neighbouring countries [14, 15]. In many countries effective access to MT remains severely limited [14, 15]. In addition, many of the MT-treated patients are treated too late for a good functional outcome because of logistic delays that include, in many cases, transportations to remotely located comprehensive stroke centres (CSCs, Level 1 stroke centres) [10–13]. Time to intervention is critical: patients revascularized ≤ 2 h achieve ~90% good functional neurological recovery, whereas the recovery associated with the commonly encountered delays of ≥ 6 h is considerably less, yielding ~20% [8, 9]. Thus any healthcare system that mandates transporting patients to (scarce) CSCs rather than treating them (if feasible) locally [16] introduces unnecessary treatment delays that

translate into poorer clinical outcomes [10, 16]. Lack of physicians able to deliver MT in a timely fashion [1] and limiting MT procedures to the few sites with neuroradiology facilities [17] have been identified as fundamental causes of inadequate MT delivery.

Interventional cardiologists already provide a fully operational infrastructure with 24/7/365 service and large volume interventional service for patients with acute myocardial infarction and are highly skilled at reopening occluded arteries [18, 19] – something neurointerventionists rarely do outside of acute ischaemic stroke treatment [1], arguably making the cardiologist equally if not better suited to perform safe and effective MTs [1, 19]. Cardiologists who embark on providing MT are familiar with the differences between acute stroke and acute myocardial infarction, and they are well aware that cerebral arteries are not coronary arteries [20, 21]. They are also aware of the need for training in navigation through the cerebral vessels as well as stroke-specific and MT-specific training [20, 21].

A long-awaited Position Paper from the European Society of Cardiology (ESC) Council on Stroke and the European Association for Percutaneous Cardiovascular Interventions on interdisciplinary management of acute ischaemic stroke, developed with the support of the European Board of Neurointervention (abbreviated below as ESC/EAPCI/EBNI Position Paper on interdisciplinary acute ischaemic stroke management) [22] fills an important gap in systematically enabling interventional cardiologists to support stroke intervention in the geographic areas of unmet needs [14, 15, 22] in particular. The present document [22] stems from an earlier ESC Position Paper devoted to larger aspects of cardiology participation in stroke primary and secondary prevention that have been an unquestionable part of this specialty training, and performance, over decades, now highlighting the need to strengthen the stroke neurology-cardiology crosstalk in post-stroke patient work-up [23, 24].

One significant strength of the present ESC Position Paper [22] is the European Board of Neurointervention (a co-developer of the document) recognition of the unmet needs in MT deliverability resulting from the shortage of MT centres and physicians in many geographic areas [22]. Equally important is the European Board of Neurointervention acknowledgement that trained cardiologists “can” deliver MTs (“Interventional cardiologists

adequately trained to perform endovascular stroke interventions could complement stroke teams to provide the 24/7 on call duty and thus to increase timely access of stroke patients to endovascular treatment") [22], concluding the discussion on who "should" or "be allowed" to deliver MT [25–30]. The document rightly states that "training of interventional cardiologists to treat AIS patients using standard requirements will contribute to achieve broad access to endovascular stroke treatment, especially in regions and countries which are lacking this 24/7 service" [22]. The need to continue establishing Level 2 centres (thrombectomy-capable stroke centres, treating ≥ 100 stroke patients per year and performing ≥ 50 stroke thrombectomies per year) [22] is clearly, and rightly, voiced in the document – along with the need of travel for MT distance not exceeding (if feasible) 1 h and the need of at least 2 MT centres per million population, adequately distributed across the country [22]. The document [22] rightly recognizes that there is no need for on-site neurosurgery in Thrombectomy-Capable Stroke Centres (Level 2 centres). Indeed, majority of centers in Mr CLEAN and other pivotal trials of MT [31] did not (and do not) have on-site neurosurgery. This terminates the misconception [32] of on-site neurosurgery "need" to deliver MT to stroke patients, in line with the recent American Heart Association/American Stroke Organization guidelines, which clearly indicate that stroke MT treatment should not be limited to neuroradiology-run Comprehensive Stroke Centres: "Regional systems of stroke care should be developed. These should consist of the following: (a) Healthcare facilities that provide initial emergency care, including administration of i.v. alteplase, and, (b) *Centers capable of performing endovascular stroke treatment* with comprehensive periprocedural care to which rapid transport can be arranged when appropriate (Class of recommendation I, Level of evidence A)". One more important strength of the present ESC Council on Stroke/EAPCI/EBNI position paper [2] is that it lists fundamental quality assurance thresholds. These include (1) successful recanalisation (modified TIC1 2b or 3) in at least 60% of cases, (2) embolization to new territory of $< 15\%$, and (3) symptomatic intra-cranial haemorrhage (i.e. parenchymal haematoma on imaging with clinical deterioration) rate $< 10\%$. Unfortunately, other quality assurance thresholds directly linked to patient outcome, such as the time to device deployed, time to recanalization as well as pre-, peri- and postprocedural blood pressure management, are not presently considered [22]. Furthermore, the timeline to completed workup of underlying causes, specifically of cardiac and extracranial origins [23], is not listed [22].

An important step backwards in the current ESC/EAPCI/EBNI position paper [23] is its drift away from previous positions [33], with the present inexplicable lack of recognition of operator experience in carotid artery stenting (CAS). Irrespective of the CAS experience of the

operator, the ESC/EAPCI/EBNI document proposes an unrealistic training quota that includes the new need to perform a minimum of 50 MTs in training (at least 25 as first operator) [22]. Despite the title suggestion that the ESC/EAPCI/EBNI Position Paper on interdisciplinary acute ischaemic stroke management is based on "evidence" [22], no clinical (or other) evidence has been provided to support these unrealistic numbers. On the other hand, there is the real-life evolution of cathlab cardiology services that safely and effectively add MT to their routine high-volume CAS service in order to address the urgent need for this life-saving treatment [24, 34–38]. Indeed, one in five acute ischaemic stroke patients have a proximal internal carotid or vertebrobasilar artery pathology in mechanistic relation to stroke [22]. Obviously, if an operator already has experience in CAS, they are experienced in navigating the most challenging supra-aortic vessels (including balloon catheter use) and do not need to (re-)train these skills in order to perform MT [1, 18, 19, 24, 34, 38]. A prior position clearly recognized experience in carotid stenting (≥ 25 procedures as first operator) and listed 10 acute stroke thrombectomies as sufficient credentialing [33]. If the present document requirements, including the need to perform 50 MTs in order to be able to start delivering MTs as part of a Thrombectomy-Capable Stroke Centre service [22], were introduced in a country that does not have an adequate number of physicians performing MT, the recommendation of 50 MT procedures will be prohibitive to expand the service. Consequently, this number must be seen as unrealistic. This ESC/EAPCI/EBNI direction also strongly contrasts with the North American approach. The US Joint Commission statement (2019) [39] suspended the USA operator training and volume requirement as they recognized them to be unrealistic, given the need to urgently expand MT services. Similarly, no minimum number of MTs within the training requirements is listed in the recent Training Guidelines for Endovascular Ischemic Stroke Intervention Multi-Society Consensus Document [40].

Poland is a country where the shortage of MT centres and operators results in severe under-treatment of the Polish MT stroke population [17, 28–30]. The MT rate in 2020 was as low as $\sim 3.1\%$, compared to 7.5–8.1% in the neighbouring Czech Republic and Germany (both systems have cardiologist participation [34, 37, 41]). With a population of 38 million, this difference translates to at least 2500 disabilities that could have been – but were not – prevented over the last 3 years [17]. This estimate does not take into consideration further disabilities resulting from MT delays due to patient transportation [10–13, 16] (about 0.5 thrombectomy-capable centres per one million population in Poland [40], in contrast to the recommended two centres per million [22]).

It is clear that procedure-related patient safety cannot be compromised. However, it is also obvious that pa-

tients who can be treated locally with MT should not be transported to another centre [19, 24, 42], losing their MT benefit (brain) on the way [8, 9, 13].

MT equals cerebral resuscitation [17]. Large-vessel occlusion causes (focal) brain ischaemia [2]. This is in many ways analogous to global brain ischaemia as a result of cardiac arrest. There is no doubt among specialists and lay people that, in case of a cardiac arrest, cardio-pulmonary resuscitation is needed as quickly as possible. No one in this scenario would suggest referring patients (with arrested blood flow to the brain) to sparse regional resuscitation centres of excellence [17].

As a model solution for a developing system, following multispecialty consultations, Thrombectomy-Capable Stroke Centres and noninterventional radiologist operator requirements have been recently agreed on and set in Poland as a Minister of Health Ordinance [42]. Requirements for interventionalists who are not neuroradiologists include, among other training, participation in at least 150 carotid or intracranial artery interventions with 50 procedures as the first operator (5 of which are intracranial, proctorship accepted). The need to enhance MT deliverability was recently echoed by the 2021 position paper on stroke thrombectomy by the Chamber of Physicians (Poland) [43]. It states that having proven skills and practical experience of performing MT is what matters – not the medical specialty. The document [43] further states that, as a life-saving and disability-preventing procedure, MTs performed in Thrombectomy-Capable Stroke Centres should be reimbursed to the hospitals by the National Health Fund, similarly to reimbursement to the Comprehensive Stroke Centres listed by the Minister of Health [43].

In contrast to elective procedures, MT is a procedure that cannot be “arranged” for training in a desired time and location. Operator experience in CAS en route to MT should be recognized and result in a shorter pathway to becoming certified in MT [19, 33]. In light of recent evidence showing no excess complications in MTs performed by cardiologists (and those with CAS experience in particular) [34–37]) the presently suggested unrealistic “first operator” MT delivery requirements including 50 prior MTs [22] should be replaced or suspended.

Further evolution of the ESC/EAPCI/EBNI Position Paper on interdisciplinary acute ischaemic stroke management [22] should take into consideration the regional needs and variations, with the Polish accreditation system allowing for combined CAS and MT cases in operator credentialing [42] serving as a potential model. While “hands-on” experience in treating real-life patients with MT remains fundamentally necessary, operator requirements should include other forms of training that are already effective in other areas of interventional medicine. These include supervised simulator and cadaveric model training with varying clinical and anatomic scenarios

and complications [44, 45] as well as remote proctorship and multispecialty team training [46, 47]. Implementation of visual decision-aiding tools [48] and MT outcome prediction models [49] should also be included. Strict quality assurance remains a must to ensure patient safety [22, 42].

All in all, while the present document offers some important contributions, the next steps are urgently needed to deliver MT to stroke patients more effectively [50].

Conflict of interest

PM is the Polish Cardiac Society Board Representative for Stroke and Vascular Interventions. Other authors declare no conflicts of interest in relation to this paper.

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